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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/772,520	01/29/2001	Francis L. Garing	DEKA:276US/MBW	9753

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EXAMINER

MEHTA, ASHWIN D

ART UNIT PAPER NUMBER

1638

DATE MAILED: 01/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s) N .

09/772,520

Applicant(s)

GARING, FRANCIS L.

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,5-13 and 15-20 is/are allowed.
- 6) ☒ Claim(s) 3,4,14,21 and 24-31 is/are rejected.
- 7) ☒ Claim(s) 22, 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objection to the specification for the presence of blank lines is withdrawn, in light of the amendment replacing the lines with an ATCC accession number.
3. The rejection to claims 1-31 under 35 U.S.C. 112, 1st paragraph, under item 4 of the Office action mailed 25 September 2002 is withdrawn, in light of the Declaration of Biological Culture Deposit received 18 November 2002.

Claim Objections

4. Claims 22 and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

5. Claims 3, 4, 14, and 21 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed 25

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September 2002 under item 2. Applicant traverses the rejection in the paper received 18 November 2002. Applicant's arguments were fully considered but were not found persuasive.

Regarding the rejection of claims 3 and 4, Applicant argues that it is not necessary that the population of claim 2 be an essentially homogenous population of seed, and that the population of claim 2 may potentially include a small amount of other seed, yet still comprise a population of seed of corn variety I026458 (response, page 5, 3rd and 4th paragraphs). However, there is no indication in claim 2 that the population can comprise other seed. Claim 2 is not directed to a population of seed comprising seed of the corn variety of I026458. It is drawn to a population of seed of the corn variety of I026458. There is nothing to indicate that any other seed variety is in that population.

Regarding the rejection of claim 14, Applicant argues that while it is true that I026458 seed can only produce I026458 plants, it is not required that a population of seed [plants] produced by growing I026458 seeds only contains I026458 plants. To explain this statement, Applicant cites an example in which a collection of I026458 seed used to plant the population of I026458 plants may contain small amounts of other kinds of seed. Or alternatively, other types of plants, such as weeds, may grow within a population of plants that are grown (page 6, 1st paragraph). However, the claim clearly states that the population of corn plants is produced by growing seed of the corn variety of I026458, not a contaminated collection of I026458 seed. The claim makes no mention of any other seed. Therefore, the only plant that can be in a population of plants grown from seed I026458 is an I026458 plant. It does not matter that some other plant may grow next to a I026458 plant, as the other plant was not produced by growing a I026458 seed.

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Regarding claim 21: Applicant argues that the specification defines "crossing" as "The pollination of a female flower of a corn plant, thereby resulting in the production of seed from the flower," and that in light of this definition that it is clear that crossing in claim 21 is done one time. Applicant argues that claim 21 specifies that "seed is allowed to form", and that if multiple generations were involved the claim would have to specify that after the seed is formed, it is planted and crossing takes place again (response, page 6, 3rd paragraph). However, the term "comprising" in line 1 of claim 21 indicates that the claimed process may contain more than just the stated step. Further, dependent claim 22 further defines the process of claim 21 as a process of producing F1 hybrid corn seed, which indicates that the process of claim 21 can involve other steps. As Applicant admittedly intends for the seed produced by claim 21 to be an F1 generation, it is again suggested that the claim be amended by inserting --F1-- in line 1 before "corn seed", so that the claim clearly indicates this.

6. Claims 3, 4, 14, 21, and 24-31 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 25 August 2002 under item 3. Applicant traverses the rejection in the paper filed 18 November 2002. Applicant's arguments were fully considered but were not found persuasive.

In response to the aspect of the rejection concerning the description of non-I026458 seeds in an essentially homogenous population of I026458 seeds, Applicants argue that they note that

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the Office has issued more than 75 patents including claims to populations of corn seed of a given variety, and that the impetus of the instant rejection is therefore not understood.

Applicants also argue that the identity of other seed included in a population of I026458 seed is irrelevant, that the fact that the population may be contaminated with other seed hardly takes the claim out of compliance with written description (response, page 7, 1st and 2nd full paragraphs).

However it is pointed out that claim 2, which is directed to a population of I026458 seed, is not included in this rejection, as the claim does not indicate that the population is comprised of any other seed besides I026458 seed. This is not inconsistent with past Office practice. Further, the allowability of claims in any given patent is decided based on the fact patterns present within the application that presents those claims, not on the fact patterns of other applications.

Furthermore, contrary to what Applicant believes, the other members of an “essentially homogeneous population” need to be described, as all members of the population are encompassed by the claim.

Regarding other issues raised in the rejection, Applicants argue the specification provides a detailed description of hybrid 7041221, which was produced with I026458 as one inbred parent, and that the description of this hybrid along with the fact that any hybrid derived from I026458 will contain half of its genes is more than adequate to provide a description of hybrid plants and seeds (response, paragraph bridging pages 7-8). Applicants cite *The Regents of The University of California v. Eli Lilly* and argue that all of the members of the claimed genus of hybrids having I026458 as one parent share the identical structural feature of having the genetic complement of I026458 (paragraph bridging pages 8-9. However, hybrid 7041221 is just one species of the rather broad genus of all hybrid plants and seeds that can be produced by crossing

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I026458 to any other corn plant. The morphological and physiological traits of 7041221 are not representative of all of the hybrids encompassed by the claims. That any hybrid plant will inherit half of its genes from I026458 does not provide sufficient information of how those genes or its products will be affected by or interact with the genes and their products inherited from the other parent. The fact that any hybrid plant will inherit half of its genes from I026458 then does not provide sufficient information of the morphological and physiological characteristics expressed by that hybrid plant. Most of the traits of I026458 described in the specification are not governed by a single gene, and so the knowledge that the claimed hybrids have inherited half of its genes from I026458 does not provide any information concerning the morphological and physiological traits of the hybrids. One cannot describe all of the morphological and physiological characteristics of corn plant 7041221 that also definitely will be expressed by other hybrids, nor can one describe the characteristics that will be different. Further, all of the hybrids having I026458 as one parent must also have inherited half of its genes from the other parent. However, descriptions of the other parents are lacking. The other parent of only a single species of the broad genus of hybrids encompassed by the claims is described, which is the other parent for 7041221 (specification, page 53, lines 17-20).

Applicants argue that the specification provides an SSR genetic marker profile of I026458 in Table 6, and that because plant I026458 is an inbred all hybrid plants will have these same SSR genetic markers and thus will be genetically distinct and identifiable from any other corn plant. (response, page 8, 1st full paragraph). However, the presence of these SSR markers does not describe the morphological and physiological traits expressed by the hybrids. None of these markers have been linked to any expressed traits. The structures of these markers have not

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been correlated with any expressed traits. Further, Table 6 shows that at least two other corn plants share many of the same loci, and so these shared loci do not distinguish the claimed plants from other plants. It is also noted that the specification does not describe the sequences of the primers that were used to produce this SSR profile, nor the PCR conditions one would need to conduct the experiments. The specification indicates at page 64 that the primers are from Celera Amgen. However, the sequences of the primers are not described, and it is not clear if these primers are freely available to the public, and if they would remain so for the term of a patent should one issue from the instant application. Further, without a description of the sequences of the SSR, one cannot confirm that the same SSR has been detected.

Applicants also argue, concerning the claimed plants further comprising single locus conversions and transgenes, that they have more than adequately described plants that comprise essentially all of the desired morphological and physiological characteristics of I026458 by way of descriptions of I026458 (response, page 9, 1st and 2nd paragraphs). However, the claims broadly encompass the introduction of genes that have not been discovered or isolated. Such genes are clearly not described by the specification. Further, the description of I026458 does not describe the morphological and physiological characteristics of the claimed plants, as the impact that the single locus or transgene has on the plant depends on the product encoded it, and its interaction with other plant products, among other considerations. It is incorrect to generally and simply conclude that a plant having just one extra gene would still essentially have all of the morphological and physiological traits as the same plant without that gene. Applicants also argue that the rejection ignores the methodology for creating single locus conversions and transgenic corn plants, and that single locus traits for conferring male sterility, waxy starch,

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herbicide resistance, etc. are described (response, page 10, 1st paragraph to page 11, 1st full paragraph). However, a method of producing a product does not describe the product itself. Applicants argue that they do not have to describe every possible single locus conversion (response, paragraph bridging pages 11-12). However, the specification cannot describe genes that have not been discovered. Applicant argues that the specification provides an adequate description of single locus conversion. But the specification does not provide the source where one may obtain all of the genes that are listed in the specification. For example, Applicants response indicates that the specification describes the single locus that confers "yield stability"(response, page 10, 1st paragraph). While the specification includes this in a list of single loci, it does not provide the sequences of the loci itself, or an indication that the prior art teaches that they have been isolated at the time the instant invention was filed. For example, a single locus that confers yield stability is not known. It is suggested that the claims drawn towards plants comprising single locus conversions be amended to recite the types of single genes that confer traits contemplated in the specification, for example genes conferring viral resistance, or male sterility, provided the prior art teaches that those types of genes have been isolated and therefore reduced to practice.

Summary

7. Claims 3, 4, 14, 21, and 24-31 remain rejected. Claims 22 and 23 are objected. Claims 1, 2, 5-13, and 15-20 are allowed.


8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

January 20, 2003


ASHWIN D. MEHTA, PH.D
PATENT EXAMINER